

GE Healthcare 510(k) Premarket Notification Submission

K101874

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: June 28, 2010

Submitter: GE Healthcare [GE Medical Systems Ultrasound and Primary

Care Diagnostics, LLC] 9900 Innovation Dr Wauwatosa, WI 53226

Primary Contact Person: Bryan Bchn

Regulatory Affairs Manager

GE Healthcare, GE Medical Systems Ultrasound and Primary

Care Diagnostics, LLC.] T:(414)721-4214

F:(414)918-8275

Secondary Contact Person: Jim Turner

Regulatory Affairs Manager America's Service

GE Healthcare, GE Medical Systems Ultrasound and Primary

Care Diagnostics, LLC T:(262) 544-3359 F:(414)908-9225

Device: Trade Name: LOGIQ P6/P6 Pro BT11 Ultrasound System

Common/Usual Name: LOGIQ P6/P6 Pro BT11

Classification Names:

Product Code:

Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO

Diagnostic Ultrasound Transducer, 24 CFR 892.1570, 90-fTX

Predicate Device(s): K073297 GE LOGIQ P6 Ultrasound System

K092271 GE LOGIQ E9 Diagnostic Ultrasound System

Device Description:

The subject device consists of a mobile console with keyboard, specialized controls, a color video LCD display with electronicarray transducers. It has the same general appearance, dimensions and weight as the unmodified device, it is a Track 3 generalpurpose imaging and analysis system providing real-time digital acquisition, processing and display capability intended for general radiology imaging and evaluation with some cardiology

and vascular applications.

Intended Use:

The device is a general-purpose ultrasound system. Specific clinical applications and exam types include: Fctal; Abdominal (renal & GYN/pelvic); Pediatric; Small Organ (breast, testes,

29



GE Healthcare 510(k) Premarket Notification Submission

thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transesophageal (TE); Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic, vascular and neuro.

Technology:

The LOGIQ P6 BT11 employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Determination of Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform with applicable medical device safety standards. The LOGIQ P6/P6 Pro and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final Acceptance Testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, LOGIQ P6/P6 Pro, did not require clinical studies to support substantial equivalence.

Conclusion:

GE Healthcare considers the LOGIQ P6/P6 Pro to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES



Food and Drug Administration 10903 New Hampshire Avenue Document Mail Center - WO66-G609 Silver Spring, MD 20993-0002

Mr. Bryan Behn
Regulatory Affairs Manager
GE Healthcare
GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC
9900 Innovation Dr.
WAUWATOSA WI 53226

OCT - 5 2010

Re: K101874

Trade/Device Name: LOGIQ P6/P6 Pro BT11 Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: July 26, 2010

Received: September 10, 2010

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the LOGIQ P6/P6 Pro BT11 Ultrasound, System as described in your premarket notification:

Transducer Model Number

<u>i12L</u>		<u>3Sp</u>
ML6-15		<u>5Sp</u>
<u>4D8C</u>		<u>6Tc</u>
4D5C-L	•	<u> 11L</u>
3CRF		BE9CS

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6881.

Sincerely yours,

David G. Brown, Ph.D.

Acting Director

Division of Radiological Devices
Office of *In Vitro* Diagnostic Device

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Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)



K101874

510(k) Premarket Notification Submission

510(k) Number (if known): K101874

Device Name:

LOGIO P6/P6 Pro BT11

OCT - 5 2010

Indications for Use:

The device is a general-purpose ultrasound system. Specific elinical applications and exam types include: Fetal; Abdominal (renal & GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transesophageal (TE); Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracie, vascular and neuro).

Prescription Use X AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use_NA_ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) Number K101874

Page 1 of 1

5



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form GE LOGIQ P6/P6 Pro Ultrasound System

Inlended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Π					Mode of	Operation				
Anatomy/Region of Interest	В	M	PW Doppler	CW Doppler	Calor Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other
Ophthalmic		-									
Fetal / Obstetnes	Р	P	Р		P	Р	P	P	Р	р	P
Abdomina#II	P	Р	P	P	P	Ρ	P	P	P	ρ	P.[6]
Pediatric	Ρ	P	P	Р	P	P	Р	Р	Р	P	P.[6]
Small Organi7	Р	Р	P		Р	Р	Р	P	P	P	[6]
Neonalal Cephalic	P	P	Р		P	P	Р	P	P	Р	 -
Adult Cephatic	P	P	Ρ	P	Р	Р	Р	Р	Р	P	
Cardiac ⁽³⁾	P	P	P	Р	P	P	Р	P	P	P	
Peripheral Vascular	P	Р	P		P	Р	P	P	Р	P	[6]
Musculo-skeletal Conventional	P	Р	Р		P	Р	P	P	Р	Р	[6]
Musculo-skeletal Superficial	Р	Р	P		Р	Р	Р	Р	P	Р	(6)
Other(4)	Р	Р	Р	P	Р	Р	Р	Р	Р	Ρ	Р
Exam Type, Means of Access	Π					<u> </u>					
Transesophageal	P	Р	Р	P	Р	Р	Р	Р	P	P	
Transrectal	P	P	P		P	i -	Ρ	P	Р	Р	Р
Transvaginal	P	P	P		Р		Р	Р	Р	Р	Р
Transuretheral		Ι-									
Intraoperative ^[5]	P	P	Р		P	Þ	Р	P	Р	Р	[6]
intraoperative Neurological	P	Р	P		P	Ρ	Р	Р	P	Р	[6]
Intravascular					<u> </u>						T
Laparoscopic								<u> </u>			

N = new indication, P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

- [2] Small organ includes breast, testes, and thyroid.
- [3] Cardiac is Adult and Pediatric
- [4] Other use includes Urology/Prostate
- [5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
- [6] Elastography Imaging
- [7] Combined modes are Bild, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- (**) Other mode is 4D / Realtime 3D

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CER 801.109)

17

For David 6. Brown

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

K101874



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P6 with i12L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application						Made of	Operation				
Anatomy/Region of interest	В	М	PW Doppler	CW	Color Doppier	Color M Doppler	Power Doppier	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	ļ										
Abdominal ⁽¹⁾	Ľ		Γ.		T						
Pediatric	P	P	Р		P	Ρ	Р	Р	Р	Р	1
Small Organi ²	Р	Р	P		P	P	Р	Р	Р	Р	
Neonatal Cephalic						_					
Adult Cephalic					'						
Cardiac ^[3]	l	-									
Peripheral Vascular	ρ	Ρ	Р		P	P	P	P	Р	P	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^{MJ}	1	_			T -						
Exam Type, Means of Access											
Transesophageal			Γ		f -						
Translectal			Γ	L	l						L
fransvaginal	Ľ	l	<u> </u>				<u> </u>		l		
Transuretheral	abla	Ţ	T	(Γ	[[Ţ
Intreoperative ^(a)	P	P	Р		Р	Ρ	P	Р	P	P	
Intraoperative Neurological	E	E	E		E	E	E	E	E	E	
Intravascular							<u> </u>				
Laparoscopic										·	

N - new indication: P = previously deared by FDA (Logiq 9 K030934); E - added under Appendix E

Notes. [1] Abdominal includes renal, GYN/Pelvic

- [2] Small organ includes breast, testes, and thyroid.
- [3] Cardiac is Adult and Pediatric
- [4] Other use includes Urology/Prostate
- [5] Intraoperative includes abdomnal, thoracic (cardiac), and vascular (PV).
- [1] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD,

[*] Other mode is 4D / Realtime 3D

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

18

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P6 with ML6-15 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application						Mode of	Operation		_		
Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Dopplar	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic		Ĺ.		Ĺ					_		
Fetal / Obsterrics	\perp										
Abdominal ⁽¹⁾	Γ	Γ	Γ								
Pediatric	Р	P	P		P	P	Р	Ρ	Р	Р	(6)
Smail Organizi	P	P	Р		P	ρ	Ρ.	Р	Р	Р	[6]
Neonatal Cephalic											
Adult Cephalic			·								
Cardiac ^[3]	Γ		T								
Peripheral Vascular	P	P	Р		Р	þ	Р	Р	Р	Р	[6]
Musculo-skeletai Conventional									1		
Musculo skeletal Superhoal											
Other ⁽⁴⁾	İ	\Box								[
Exam Type, Means of Access											
Transesophageal	\Box		Ι								
Transrectal	\prod		L	<u> </u>			<u> </u>			<u> </u>	
Transvaginal	<u> </u>										
Transuretheral] -			
Intraoperativa(5)											
Intraoperative Neurological											
Intravascular											<u> </u>
Laparoscopic	Γ		1	1							

N * new indication; P = previously cleared by FDA (LOGIQ E9 K092271); E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

- [7] Small organ includes breast, testes, and thyroid.
- [3] Cardiac Is Adult and Pediatno
- [4] Other use includes Urology/Prostate
- [5] intraoperative includes abdominal thoracic (cardiac), and vascular (PV)
- [6] Elastography unaging
- [1] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- [7] Other mode is 4D / Realtime 3D

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Prescription User (Per 21 CFR 801.109)

19

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(Division Sign-Off)
Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

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510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P6 with 4D8C Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	\Box					Mode of	Operation				
Anatomy/Region of Interest	8	м	PW Doppter	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Othe
Ophthalmic											
Fetal / Obstetrics											
Abdominaliii			T								
Pedialric	Р	P	Р		P	Р	P	Р	P	P	P
Small Organizi		Г							.,		
Neonatal Cephalic											
Adult Cephalic										_	
Cardiac ^[3]							i — —				
Peripheral Vascular		Г				-					
Musculo-skeletal Conventional							Ī				
Musculo-skeletal Superioral										_	
Other ^{#1}	1		1		 						
Exam Type Means of Access											
Transesophageal				[_	<u> </u>				
Transrectal]								
Transvaginal											<u> </u>
Transuretheral						{					<u> </u>
Intraoperative#I		1									
Intraoperative Neurological											
Intravascular								<u> </u>			
Laparoscopic	T	T		<u> </u>							_

N = new indication; P = previously cleaned by FDA (1.0GiQ 9 Ku61129); E = added under Appendix F

Notes [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, and thyroid

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

[7] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

[**] Other mode is 4D / Realtime 3D

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Prescription User (Per 21 CFR 801.109)

20

For Duvid 6 Brown

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 101879



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P6 with 4D5C-L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cārical Application	L					Mode of	Operation				
Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppter	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic)							
Fetal / Obstetrics	Ē	E	E	·	E	E	E	E	E	E	E
Abdominali1	E	E	E		E	E	E	Ę€	E	E	E
Pediatno	Ē	E	E		E	E	E	E	E	E	E
Small Organi ²											
Neonatal Cephalic											
Adult Cephalic			Ĭ								
Çardiac ⁽³⁾								<u> </u>			L^{-}
Peripheral Vascular											
Musculo-skeletal Conventional	-										
Musculo-skeletal Superficial											
Other(4)	E	E	E		E	Ē	E	E	E	Ę	E
Exam Type. Means of Access											
Transesophageal	l									L	<u> </u>
Transrectal	\Box	I	Γ								
Transvaginal							<u> </u>			L	<u> </u>
Transuretheral	(L								Ĺ	L .
Intraoperative ^[5]	L							<u> </u>		L	1
Intraoperative Neurological									<u> </u>		
Intravascular									L. <u> </u>		<u> </u>
Laparoscopic		Т	T	I	\		_	\			

N = new indication, P - previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYNIPelvic

[2] Small organ includes breast, testes, and thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[5] intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

[7] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

[**] Other mode is 4D / Realtime 3D

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

21

For David G Brown

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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510K



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P6 with 3CRF Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application						Mode of	Operation				
Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Cofor Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Othe
Ophthalmic											
Fetal / Obstetrics	Р	Р	P		Ρ	Р	Р	Р	P	Р	
Abdominal ⁽¹⁾	P	P	P		Р.	Р	Р	Р	Р	P	
Pediatric					i -						
Small Organia)											
Neonatal Cephalic							[
Adult Cephalic						_					
Cardiac ^[3]]			
Peripheral Vascular	Γ										
Musculo-skeletal Conventional	-		Ţ						_		
Musculo-skeletal Superficial											
Other ^[4]	Р	P	Р		Р	Р	Ρ	P	Р	P	
Exam Type, Means of Access]									
Transesophageal											
Transrectal						_					
Transvaginal	Γ										
Transuretheral					ļ .—						
Intraoperative ^(L)		L									
Intraoperative Neurological											
Intravascular											
Laparoscopic			T -								<u>L</u>

N = new indication; P - previously cleared by FDA(LOGIO E9 KU92271); E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

- [2] Small organ includes breast, testes, and thyroid.
- (3) Cardiac is Adult and Pediatric
- [4] Other use includes Urology/Prostate
- [5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [1] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

[*] Other mode is 4D / Realtune 3D

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Prescription User (Per 2) CFR 801.109)

22

- for David 6. From

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101874



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P6 with 3Sp Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application						Mode of	Operation				
Anatomy/Region of Interest	8	ж	PW Doppter	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes'	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											<u> </u>
Fetal / Obstetrics								_			<u> </u>
Abdominal ¹	E	E	E	E	E	E	Ε	E	E	E	
Pediatric		Γ					T				
Small Organi2l											
Neonatal Cephalic											
Adult Cephalic	E	E	E	E	E	E	E	E	E	E	
Cardiaci ²	E	E	Ę	E	E	E	E	E	E	E	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial										_	
Other ¹⁴	T		1]			1			
Exam Type, Means of Access		Ĺ									
Transesophageal			T		7						
Transrectal											
Transvaginal								<u> </u>			
Transuretheral	1	Π		Γ		ļ					\
Intraoperative ^[5]							Ţ				Γ
Intraoperative Neurological											
Intravascular	T-		1	i			1		_		
Laparoscopic				<u> </u>							

N = new indication; P previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, and thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

[¶ Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

Other mode is 40 / Realtime 30

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Concurrence of CDRH, Office of Device Evaluation (QDE)

Prescription User (Per 21 CFR 801.109)

23

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Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K_K161874



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE LOGIO P6 with 5Sp Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	<u>L_</u>					Mode of	Operation				
Anatomy/Region of Interest	В	М	PW Doppier	CW Doppter	Calar Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetnics			[:]
Abdominally								_ ·	ì		
Pediatric	Ē	E	E	E	E	E	Ē	E	E	E	Γ
Small Organi ²¹											
Neonatal Cephalic	L.		Ī				ĺ				
Adult Cephalic	E	E	E	E	E	E	E	E	E	E	
Cardiac ⁽³⁾	E	E	E	É	E	E	E	E	É	E	
Penpheral Vascular	Ţ	П									
Musculo-sketetal Conventional							[
Musculo-skeletal Superficial	_										
Otherl ⁴ f	Γ										
Exam Type, Means of Access											ļ
Transesophageal	L.	_	J	L				<u></u> ,		<u> </u>	<u> </u>
Transrectal	L	Ĺ_		<u> </u>		L		ļ <u> </u>			ļ
Transvaginal	L.	[<u> </u>								<u> </u>
Transuretheral		_	<u> </u>				<u> </u>				
Intraoperative ⁽⁵⁾					1			1			<u> </u>
Intraoperative Neurological											<u> </u>
Intravascular		L						<u> </u>	<u> </u>		<u> </u>
Laparoscopic			1		1						

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes. [1] Abdominal includes renal, GYN/Pelvid

[2] Small organ includes breast, testes, and thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

(5) Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

[1] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(*) Other mode is 4D / Reatime 3D

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

24

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(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

810K_K101874



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P6 with 6Tc Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Γ			_		Mode of	Operation				
Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Cator Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Integring	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetnes		1_									
Abdominal ^[1]						_					<u> </u>
Pediatric	Γ					 					
Small Organ ^{LI}											
Neonatal Cephalic			<u> </u>								
Adult Cephalic		Γ									
Cardiaci ³	Р	P	Р	Р	P	Р	Р	Р	P	£.	
Peripheral Vascular	\Box		Ţ <u> </u>								
Musculo-skeletat Conventional						\					
Musculo-skeletat Superficial											
Other ^[4]					1						
Exam Type. Means of Access	Π										
Transesophageal	P	P	Р	P	P	Р	P	P _	Р	P	
Transrectal							Ţ				
Fransvaginal	Τ	Π	Γ					Γ			
Transurethera	1	П	T								
Intraoperative[5]			<u> </u>								1
Intraoperative Neurological											
Intravascular					Ţ						
Laparoscopic	1	Г	1								

N = new indication; P = previously cleared by FDA(LOGIQ E9 K092271); E - added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, and thyroid.

[3] Cardiac is Adult and Pediatric

[4] Other use includes Urology/Prostate

[5] htraoperative includes abdominal, thoracc (cardiac), and vascular (PV).

[] Combined modes are BIM, BiColor M, BIPWD or CWD, BiColor/PWD or CWD, BiPower/PWD.

[**] Other mode is 4D / Realtime 3D

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.100)

25

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Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

310K_P101874



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE LOGIO P6 with 11L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	L					Mode of	Operation				
Anatomy:Region of Interest	В	ы	PW Coppler	CW Doppler	Color Doppler	Color M Dappler	Power Doppler		Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetnes	_							l		_	<u> </u>
Abdominalty	P	P	Р		Р	P	P	P	Р	Р	[6]
Pediatric	P	P	Р		P	Р	Р	P	Р	Р	[6]
Small Organi2J	Р	Ρ	Р		Р	P	P	P	Р	Р	[6]
Neonatal Cephalic											
Adult Cephalic	\Box								<u> </u>		ļ
Cardiac ^[3]			l			<u> </u>		J			<u> </u>
Peripheral Vascular			Ι					L'			<u> </u>
Musculo-skeletal Conventional											
Muscuto-skeletal Superficial		Γ.									
Olher ^[4]	1		T		<u> </u>	Ī	<u> </u>				
Exam Type, Means of Access			<u> </u>	·		ļ	ļ	<u> </u>	ļ		Ļ
Transesophageal	<u> </u>	1_		<u> </u>	<u></u>	<u> </u>	<u> </u>		<u> </u>		<u> </u>
Transrectal		L	ļ		<u> </u>				1	L	
Transvaginal			<u> </u>	<u> </u>	<u> </u>			ļ	<u> </u>	ļ <u>.</u>	
Transuretheral	L			<u></u>		<u></u>	.	<u> </u>		ļ	↓
Intraoperative ⁽⁵⁾						<u> </u>			<u> </u>	<u> </u>	<u> </u>
Intraoperative Neurological						<u> </u>	<u> </u>				ļ
Intravascular]		<u> </u>		1		<u> </u>	↓ _
Lapatescopic			T								

N = new indication; P = previously cleared by FDA(LOGIQ E9 K092271); E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pewic

[2] Small organ includes breast, testes, and thyroid

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[5] Intraoperative includes abdominal, theracic (cardiac), and vascular (PV)

[6] Elastography Imaging

[1] Combined modes are B/M. B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(**) Other mode is 4D / Realtime 3D

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Concurrence of CORH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

26

For David 6. Brown

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

10K_K/A/8



510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P6 with BE9CS Transducer

Interided Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	L				_	Mode of	Operation				
Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppier	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Othe
Ophthalmic											
Fetal / Obsteines					1		_		 I		Γ
Abdominal ¹	E	E	Ε		E		£	E	E	E	
Pediatric	E	E	E		E		E	E	E	E	
Small Organi ²		Γ									
Neonatal Cephalic											
Adult Cephalic			Γ	_			[L			
Cardiacl ^{II}			T								
Penpheral Vascular							<u> </u>	i	1		1
Musculo-skeletal Conventional	L									L	
Musculo-skeletal Superficial											
Otheri4	E	Ε	E		E		E	E	E	E	L .
Exam Type Means of Access											
Transesophageal		<u>l</u> _	l		<u> </u>	<u></u>					
Transrectal	E	E	E		E	<u> </u>	E	E	E	E	\
Transvaginal	E	E	E		E		E	E	E	E	
Transpretheral		Γ_	Ţ						<u> </u>		<u>↓_</u>
Intraoperative ⁽⁵⁾		Г			}						<u> </u>
Intraoperative Neurological						 					
Intravascular		T_	T]		
Laparoscopic	T	Π	1	1	1			<u> </u>	<u> </u>	١ .	<u>↓</u>

N new indication; P = previously cleared by FDA(minor modification to BE9C); E = added under Appendix E

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

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Con David 6. Brown

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Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

 $p_{K} = P / O / S / S$

Notes. [1] Abdominal includes renal, GYN/Pelvic

^[2] Small organ includes breast, testes, and thyroid.

^[3] Cardiac is Adult and Pediatric.

^[4] Other use includes Urology/Prostate

^[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

^[6] Elastography Imaging

^[*] Combined modes are B/M, B/Color M, B/PWO or CWD, B/Color/PWD or CWD, B/Power/PWD

^[**] Other mode is 4D / Reathme 3D